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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,532	08/03/2001	Endre Markovits Schersl	22106965.105181	9018

51738 7590 11/29/2006

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/922,532

Applicant(s)

SCHERSL ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-63 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 56-63 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Final Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. **The rejection of claims 36-55 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is made moot by the cancellation of the instant claims.**
3. Claims 56 and 58-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite "from about 20% to about 60% by weight of 1-docosanol". The present specification lacks support for said range and, thus, does not convey to the skilled artisan in the art that applicant, at the time the application was filed, had possession of the claimed invention.

It is noted that applicant points to Table 1, the Examples and page 4, lines 21-25 for support. However, Table 1 recites a range of 2-60% and Example 2 recites a

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composition which does not contain octadecanol and, thus, differ from the instantly claimed composition.

Claim Rejections - 35 USC § 103

4. The rejection of claims 36-55 under 35 USC 103(a) over Fuenzalida et al. (EP 952,208), Jones et al. (Metabolism, 1998), Cleary (US 4,495,094), Sorkin, Jr. (US 5,952,393) and Milstein et al. (US 6,394,230) in combination is made moot by the cancellation of the instant claims.

5. Claims 56-63 are rejected under 35 USC 103(a) over Fuenzalida et al. (EP 952,208), Sorkin, Jr. (US 5,952,393), Gamble et al. (US 6,596,776), Cleary (US 4,495,094); Milstein et al. (US 6,394,230) and Jones et al. (Metabolism, 1998) in combination.

Each of Fuenzalida, Sorkin and Gamble teaches policosanols, i.e., long chained aliphatic alcohols, are useful in lowering plasma cholesterol levels (see each reference in its entirety, especially **Fuenzalida et al.**, sections 0003-0007, 0050, 0057, 0068, 0071 and 0076; **Sorkin, Jr.**, col. 1, lines 5-8; col. 3, lines 11-26; examples 1 and 2; **Gamble et al.**, col. 2, lines 4-21; col. 3, line 52 – col. 4, line 39; col. 9, lines 44-63).

Fuenzalida teaches the presence of fatty alcohols such as eicosanol, docosanol, tetracosanol and hexacosanol in tall oil (see especially Example 9, Table 4) and Cleary teaches the presence of octadecanol in tall oil (see the reference in its entirety, especially Example II).

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Each of Gamble, Milstein and Jones teaches the incorporation of the cholesterol-lowering agents, such as mixtures of aliphatic alcohols, into food substances such as margarine is known in the art (see each reference in its entirety, especially **Gamble et al.**, col. 9, lines 52-63; **Milstein et al.**, col. 1, lines 18-35; **Jones et al.**, page 751, 1st paragraph).

Based on the prior art as discussed above, the utilization of a composition comprising long chained aliphatic alcohols in lowering plasma cholesterol levels would have been obvious to the skilled artisan in the art at the time of the present invention.

The instant claims differ from the cited prior art by reciting specific ranges of eicosanol, docosanol, tetracosanol and hexacosanol with or without a specific amount of octadecanol. However, determination of the amounts of each of the alcohols in the composition that would be effective in lowering cholesterol level requires only routine experimentation which was within the level of skill of the ordinary artisan in the art at the time of the present invention. Therefore, the recitation of specific ranges of the active ingredients is not patentable absent a showing of criticality which is not present in the present specification.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

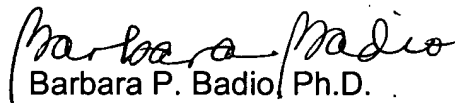
Telephone Inquiry

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB

November 27, 2006